December 17, 2020 ■ Volume 25 Issue 25

ISMP
An ECRI Affiliate

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

BUILDING BRIDGES TO SAFETY

ISMP 23RD ANNUAL CHEERS AWARDS

This month, ISMP celebrated its 23rd Annual **CHEERS AWARDS**, which recognize individuals, organizations, and groups that have demonstrated an extraordinary commitment to advancing the science and study of patient safety. This year's winners were honored at our first virtual **AWARDS** ceremony on **December 8, 2020**. Please join us in congratulating this year's **CHEERS AWARDS** winners, an impressive group of leaders who have helped create innovative solutions by building bridges to advance medication safety.

CHEERS AWARDS Winners

Mary E. Burkhardt, MS, RPh, FASHP, FSMSO, was honored with a distinct **CHEERS AWARD**, an ISMP **Volunteer Award**, for her decades of altruistic service to ISMP. She has tirelessly volunteered her time to many ISMP programs, projects, and advisory groups, and has contributed valuable suggestions and recommendations. Mary authored two chapters in ISMP's book, *Medication Errors*, 2nd Edition, and worked on the development, pilot testing, and use of ISMP's medication safety self assessments, including the *Medication Safety Self Assessment for High-Alert Medications* (www.ismp.org/node/580), and the soon-to-be launched *Medication Safety Self Assessment for Perioperative Settings*.

She also has mentored ISMP Fellows as well as other practitioners just starting out in their careers and is often called upon for advice or to answer questions. Mary has been dedicated to keeping the lines of communication open with ISMP, often taking the initiative to reach out and share new knowledge. She has been a valuable asset in helping ISMP achieve its mission. Currently, she is a National Pharmacy Executive at the Veterans Affairs (VA) National Center for Patient Safety in Ann Arbor, Michigan.

The **Choctaw Nation Health Services Authority** (CNHSA), located in rural southeastern Oklahoma, was honored with a **CHEERS AWARD** for employing a full-time medication safety officer in a unique setting, enabling the implementation of a wide range of impressive medication safety initiatives. After ISMP published a white paper in 2018, encouraging all healthcare organizations to establish a full-time medication safety position (www.ismp.org/node/1132), CNHSA expanded its auxiliary position to a full-time, dedicated professional to make past safety achievements more widespread and sustainable.

Establishment of a full-time medication safety officer position also helped CNHSA create an extensive and proactive improvement process and medication safety program unsurpassed in other tribal health organizations. A few notable medication safety initiatives include publication of a system-wide *Medication Safety Newsletter*, implementation of the *ISMP Targeted Medication Safety Best Practices for Hospitals* (www.ismp.org/node/160), and monthly review and mitigation of both internal and external medication errors and hazards. CNHSA now serves as a strong advocate for dedicating significant resources to medication safety in rural healthcare systems and has shared its experiences at a regional Indian Health Service conference.

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SAFETY briefs

Error reporting mandatory for EUA drugs. As noted in the *Fact Sheets* for therapeutic products available under an Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA), reporting of adverse events, including medication errors, is **mandatory**. Providers or their designees must report all medication errors and serious adverse events using the methods noted in the specific product *Fact Sheet* and within the specified time period. Requirements may differ depending on the drug or biological product. For example, errors related to the coronavirus disease 2019 (COVID-19) vaccines must be reported to the Vaccine Adverse Event Reporting System (VAERS, www.ismp.org/ext/608), while errors involving use of the monoclonal antibodies bamlanivimab and casirivimab/imdevimab must be reported to FDA MedWatch (www.ismp.org/ext/609). Again, be sure to consult the specific EUA product's *Fact Sheet* for the required reporting method.

One more thing—please consider informing ISMP about any errors involving these products so we can communicate any safety issues as appropriate. You can report via our website (www.ismp.org/report-medication-error) or by email (ismpinfo@ismp.org). However, with EUA products, reporting to ISMP will not replace the need for mandatory reporting to MedWatch or VAERS.

HIGH-ALERT

Paralyzing agent vial caps without warnings into 2022. Due to an increase in demand to treat critically ill coronavirus disease 2019 (COVID-19) patients on ventilators, shortages of neuromuscular blocking agents began to appear earlier this year. At the time, the US Food and Drug Administration (FDA) allowed temporary manufacturing of these drugs without the vial cap (seal) warning statement, "Paralyzing Agent," as normally required by USP and FDA (**Figure 1**, page 2), since caps with the warning statement were not available to the manufacturers.

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Einstein Medical Center Montgomery in East Norriton, Pennsylvania, was honored with a **CHEERS AWARD** for its development and implementation of a novel screening tool, the Einstein Montgomery Opioid-induced Ventilatory Impairment Assessment (EMOVIA©). There are other screening tools available to assess issues with ventilation of patients on opioids, but unlike EMOVIA, the recommended actions are physician-driven. EMOVIA interventions are nurse-driven and immediate, allowing nurses to treat patients in real time, and empowering them to intervene immediately using nursing judgment and following an established protocol.

EMOVIA is the only tool that supports the use of continuous electronic monitoring using capnography, which is considered the gold standard for managing patients at risk for opioid-induced ventilatory impairment. Implementation of EMOVIA at the medical center has helped code blues remain at zero for medical-surgical patients receiving opioids and has reduced unplanned intubations by 55% in this same patient population. The organization has shared its processes and lessons learned with the healthcare community at the regional, state, and national levels.

The **HCA West Florida Division** received a distinct **CHEERS AWARD**, an ISMP **Subscriber Award**, for the consistent distribution and use of information provided in ISMP newsletters, and the resulting improvements in medication safety across their 15 hospitals. The division's interdisciplinary Medication Safety Committee has been instrumental in implementing key safety strategies published in the ISMP Action Agenda as well as various ISMP guidelines and assessment tools.

Currently, the *ISMP Targeted Medication Safety Best Practices for Hospitals* are being used as a guide to perform medication safety audits and medication safety rounds in nursing units within each facility to identify vulnerable areas. ISMP guidelines associated with smart infusion pumps, automated dispensing cabinets, and safe electronic communication have been used to implement strategies to minimize risk. Also, participation in the *ISMP Medication Safety Self Assessment for High-Alert Medications* has resulted in dozens of division-wide improvements. In addition, order sets and policies have been standardized, and a quarterly division-wide newsletter has been created to communicate important information and progress in medication safety improvement to staff.

Tina M. Suess, MHA, BSN, RN-BC, CPHIMS, CPPS, was honored with a **CHEERS AWARD** for providing exceptional leadership in the healthcare information technology industry on a national level, as well as in her own community hospital. Over her career, she has become known as a forward-thinking expert on several medication use technologies, including barcoding access across the entire medication use process and smart pump-electronic health record interoperability. She has consistently served as a liaison between clinical and information technology services, ensuring a patient-centric approach to the use of medication safety technology.

She has participated in alpha- and beta-testing for emerging technologies, conducted research, and shared her knowledge through numerous national, state, and local presentations as well as journal publications. Tina also has provided ISMP with input on the challenges and achievements possible with infusion-related technologies, using her unique perspective on technology adaptation in a real-life setting. She is currently Manager of Medication Safety Integration for Penn Medicine Lancaster General Health in Lancaster, Pennsylvania.

George Di Domizio Award Winner

The **GEORGE DI DOMIZIO AWARD** was established in 2012 in memory of a late ISMP Board member who advocated for greater cooperation between the medical industry and the broader healthcare community to promote safer drug products. The **AWARD** was given

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The products affected include vecuronium bromide for injection in 10 and 20 mg vials from Fresenius Kabi, rocuronium bromide injection 50 mg vials from Athenex and Alvogen, and rocuronium bromide injection 100 mg vials from Alvogen. While new vials once again have caps with warnings, vecuronium vials with the temporary caps might remain in distribution until inventory is exhausted (expiration dates up to May 31, 2022). Also, rocuronium with temporary caps from Athenex and Alvogen may be around until June 2022.

Figure 1. Images of typical cap (left) and blank temporary cap (right) for vecuronium bromide injection (top) and rocuronium bromide injection (bottom) vials.

As previously noted in our June 4, 2020 newsletter (www.ismp.org/node/18346), this situation has obvious safety implications since the absence of the warning may make the vials look more like other medications with similar size vials and cap colors. Neuromuscular blocking agents are high-alert medications because of their well-documented history of causing catastrophic injuries or death when used in error. Staff awareness about the absence of the usual warning statement is critically important, as is safe handling and storage with labels, not caps, facing up. Please ensure this situation is again communicated to all relevant staff and implement the safety measures we previously recommended in our newsletter, such as affixing auxiliary "Warning: Paralyzing Agent" labels to vial caps.

HIGH-ALERT

Tranexamic acid labeling changes coming. The US Food and Drug Administration (FDA) has announced that it will be revising the labeling for tranexamic acid injection to reduce the risk of potentially fatal wrong-route errors (www.ismp.org/ext/610). Tranexamic acid has been accidentally

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The next newsletter will be published on January 14, 2021. See you next year!

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this year to **Mary Baker, PharmD, MBA, FASPEN**, for consistently serving as a valuable resource to ISMP regarding pharmaceutical product manufacturing.

Dr. Baker has more than 30 years of experience in the industry, and is currently the Senior Director, Sterile Injectables, in Pfizer's Biopharmaceuticals Group in Lake Forest, Illinois. She has provided ISMP with essential insight from the industry side and helped gather information and direct ISMP to credible sources for a wide variety of topics outside of her area of expertise. Dr. Baker has served as Vice Chair of the USP Nomenclature and Labeling Expert Committee and holds an adjunct faculty appointment at Purdue University College of Pharmacy. She has received numerous awards and honors throughout her career, including USP's Award of Recognition, Purdue College of Pharmacy Distinguished Alumna, and the Purdue Pharmacy Women's Leadership Award.

Lifetime Achievement Award Winner

One of the highlights of the evening was the presentation of the 2020 ISMP **LIFETIME ACHIEVEMENT AWARD**, given in memory of ISMP's late Trustee David Vogel, PharmD, which honors individuals who have made ongoing contributions to patient safety throughout their career. This year's honoree, **David Cousins, BPharm, MSc, FRPharmS, PhD**, has tirelessly pursued development of a safe medication policy agenda in the United Kingdom (UK) that has since been modeled around the world.

As chief pharmacist at the Derbyshire Royal Infirmary in Derby, he played a leading role in raising awareness of medication safety in the UK. Together with Dr. David Upton, Dr. Cousins wrote a monthly column on medication errors in the journal *Hospital Pharmacy Practice*. He served as head of safe medication practice at the former National Patient Safety Agency (NPSA) and then NHS England for 12 years, helping develop the National Reporting and Learning System and issue patient safety alerts. He was a key author of the "Design for Safety" publication series, illustrating how good design can help minimize risk to patients arising from labeling and packaging of medicines. He also authored a 2014 patient safety alert requiring every NHS organization in England to appoint a medication safety officer.

In 2017, as part of his work with the organization Healthcare at Home, Dr. Cousins designed and implemented a comprehensive safety incident reporting and learning system for the home care setting. He is a founding member and committee member of the International Medication Safety Network (IMSN), and during his retirement has been advising and publishing reports for the patient charity, Action against Medical Accidents (AvMA).

In his acceptance remarks, Dr. Cousins described his advocacy journey to improve medication safety in the UK. His presentation covered some of the barriers he encountered along the way, including the need for greater transparency and openness to learning about errors and addressing risk. Dr. Cousins also described how he has worked with ISMP and other organizations to shine a greater light on the need for medication error prevention.

Looking Forward

During the **AWARDS** ceremony, ISMP President **Michael Cohen** presented highlights of what ISMP has accomplished this year with your help, including the release of special free editions of the ISMP newsletter devoted to the information healthcare practitioners needed for response efforts related to the coronavirus disease 2019 (COVID-19) pandemic. Dr. Cohen emphasized that ISMP could not have achieved our shared medication safety goals without loyal supporters who submit medication and vaccine error reports to ISMP, provide us with feedback on our safety recommendations, read and incorporate the advice from our newsletters, or make a donation.

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injected instead of a local anesthetic for epidural and spinal anesthesia. Bupivacaine, ropivacaine, and tranexamic acid are sometimes packaged in vials with the same blue color cap, which has contributed to mix-ups. The FDA labeling changes will highlight the intravenous (IV) route of administration and strengthen the warnings in the prescribing information to include the risk of medication errors due to incorrect route of administration.

On September 9, 2020, ISMP, in cooperation with the American Society of Health-System Pharmacists (ASHP) and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), published a warning through the National Alert Network (NAN) about serious medication errors with tranexamic acid (www.ismp.org/node/20154). If you have not already done so, please review and implement the error-prevention measures that are outlined in this important alert.

The first five letters are not always enough. A pregnant patient visited a hospital emergency department (ED) complaining of nausea, vomiting, and stomach pain. An ED physician intended to order pyridoxine (vitamin B6), which is commonly used as an over-the-counter (OTC) agent for treating nausea and vomiting in pregnant patients. However, the physician typed the first five letters of the drug name into the computer system and inadvertently selected pyridostigmine, an acetylcholinesterase inhibitor commonly used to treat myasthenia gravis or as a reversal agent for certain neuromuscular blocking agents. The nurse caring for the patient was unfamiliar with pyridostigmine, looked it up quickly, and mistakenly believed the drug was used as a muscle relaxant (instead of used to reverse a nondepolarizing 'muscle relaxant,' as noted in product labeling). Believing the physician had ordered the drug for this purpose (relaxing muscles), the nurse administered the dose to the patient. Fortunately, oral pyridostigmine is generally considered safe to take during pregnancy, and no patient harm was reported.

The two medication names that were mixed up share several overlapping letter characters. Both start with the same six letters,

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ECRI President and Chief Executive Officer (CEO) **Marcus Schabacker** spoke about the impact that the ISMP-ECRI partnership has had on patient safety and where the field of healthcare is headed in the future. Dr. Schabacker noted that one of the biggest areas of change has been in point-of-care delivery, and that the rapid adoption of telehealth and remote care that arose during the pandemic will likely continue to expand.

A Heartfelt Thanks to All

ISMP would like to thank all of the organizations and individuals who attended and/or supported this year's **CHEERS AWARDS**. Visit www.ismp.org/node/18425 for a list of contributors and winners, and www.ismp.org/node/36 for ways you can join us in building more bridges to medication safety. If you were not able to attend this year's virtual **CHEERS AWARDS**, you can view a recording of the event posted on ISMP's website at: www.ismp.org/node/18425.

ISMP also salutes all of the healthcare heroes and essential workers who have shown bravery and resilience and gotten us through this unprecedented year. You move us, you inspire us, and we are so grateful for you. We look forward to continuing to work together on preventing medication errors and keeping practitioners and patients safe in 2021.

Prevent shoulder injuries during COVID-19 vaccinations

As our nation begins a large-scale coronavirus disease 2019 (COVID-19) immunization campaign barely a year since the deadly virus emerged in the US, it is critically important for healthcare workers who administer the vaccine to understand proper intramuscular (IM) administration technique in order to avoid a preventable and disabling occurrence called *shoulder injury related to vaccine administration* (SIRVA). This is especially important right now, as healthcare workers who may not normally administer vaccines may be called upon to help administer the new COVID-19 vaccines.

SIRVA

SIRVA is a shoulder injury triggered by the incorrect injection of a vaccine into the shoulder capsule (joint) rather than the deltoid muscle. It is caused by using an incorrect IM injection technique or improper landmarking of the IM injection site (the deltoid muscle) that results in the unintended injection of the vaccine (and/or trauma from the needle) into and around the underlying bursa of the shoulder. This results in an inflammatory process that causes injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae).[1-3]

Symptoms of SIRVA include persistent shoulder pain, weakness, and limited range of motion that typically develop within hours to a few days after receiving a vaccine; these symptoms do not improve with over-the-counter analgesics. The resulting chronic shoulder pain and inability to carry out daily activities that were possible prior to vaccination often lead patients to seek medical intervention. Patients are often diagnosed with inflammatory shoulder injuries (e.g., bursitis, rotator cuff tears, frozen shoulder syndrome, adhesive capsulitis) that do not appear to be any different than routine shoulder injuries, except that the shoulder symptoms started within days of an IM deltoid vaccination.[1]

How to Prevent SIRVA

The key to avoiding SIRVA is to recognize the anatomical landmarks for identifying the deltoid muscle and to use proper IM administration technique. Proper landmarking of the deltoid muscle requires determining the upper and lower borders of a safe injection zone. First, the patient's shoulder should be exposed completely. When a shirt cannot be removed, the sleeve should be rolled up or the arm removed from the sleeve rather than pulling the shirt's neck over the shoulder. To ensure the injection is given below the shoulder capsule, measure 2 to 3 finger widths from the acromion (bony prominence above the deltoid) to identify the upper border of the injection zone. The lower border can

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pyrido-, and end with the same three letters, -ine. When typing in the beginning of the drug name, pyrid-, both medications appeared as an option for the physician. Similarities in the product names as well as a lack of knowledge about the two medications could lead to selection errors. It is unclear what role, if any, a pharmacist played during verification of this order prior to administration. It is possible that providing the indication with the order (e.g., nausea and vomiting) would have allowed the pharmacist to realize a potential error during verification, or the nurse to realize the error when researching the unfamiliar medication.

Although the use of a specific number of letter characters (be it 4, 5, or more) can help reduce selection errors, there is no magic number regarding how many may be needed. In fact, we recently learned of a close call between phenylephrine and phenytoin because the first 5 letters are also the same. It is best to keep adding letters until the intended drug name appears distinct by itself. Also, we need to stop using the confusing term 'muscle relaxant' when referring to neuromuscular blocking agents, including in FDA-approved labeling.

HIGH-ALERT

Australia halts syringe use for vinCRIStine injection. We were pleased to learn of a labeling change last month for vinCRIStine injection in Australia. A statement has been added to the method of administration section of product labeling noting that, "Syringes should not be used for VinCRIStine Sulfate Injection administration. Preparation must be by dilution in small volume intravenous bags (the 'minibag' technique), rather than in a syringe, to protect against accidental administration via a spinal route" (www.ismp.org/ext/612).

Earlier this year, the US Food and Drug Administration (FDA) also changed the prescribing information (package insert) to call for dilution in a minibag only (www.ismp.org/node/18548). The labeling for vinCRIStine now states: To reduce the potential for fatal medication errors due to incorrect route of administration, vinCRIStine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated "FOR INTRAVENOUS USE ONLY— FATAL IF GIVEN BY OTHER ROUTES." Preparation and administration of the drug in a syringe has been removed from the package insert.

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be marked by the armpit to ensure the injection is not inserted below the deltoid muscle. 'Eyeballing' the injection site is not acceptable. The thumb and forefinger can be used to make a V to outline the deltoid muscle and keep the injection zone visible before injecting the needle at a 90-degree angle. Injections too close to the shoulder capsule can lead to SIRVA, as noted above. Injections below or too far to the side of the deltoid muscle can hit the radial or axillary nerve, respectively, which can result in neuropathy or paralysis.[1]

Multiple resources related to proper vaccination techniques are provided by the Centers for Disease Control and Prevention (CDC) and the Immunization Action Coalition (IAC). These resources have been compiled in articles by Deborah Wexler, MD, which can be found at: www.ismp.org/ext/613[2] and www.ismp.org/ext/614.[3] Many of these resources, including videos, checklists, and e-learning with continuing education credit, have been recently updated and are applicable to the COVID-19 vaccination campaign. Additionally, the University of Waterloo School of Pharmacy in Ontario, Canada, offers a helpful infographic on proper landmarking to prevent SIRVA, which can be accessed at: www.ismp.org/ext/611.[1]

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2) Wexler D. Technically speaking: Prevent shoulder injuries caused by missing the deltoid muscle when injecting vaccines! Immunization Action Coalition. Updated November 19, 2020. www.ismp.org/ext/613
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Naloxone, verapamil, and glycopyrrolate look-alike vials

We have received several reports about look-alike concerns regarding naloxone 0.4 mg/mL single-dose vials and verapamil 5 mg/2 mL single-dose vials, both manufactured by Somerset Therapeutics (**Figure 1**). An anesthesiologist recently let us know that these drug vials were being stored near one another in the anesthesia workroom's open-matrix automated dispensing cabinet (ADC), and this posed a risk of a mix-up due to their similar appearance. We also heard from a nurse who discovered vials of the drugs mixed together in the same ADC pocket.

A third product manufactured by Somerset Therapeutics, glycopyrrolate injection (0.2 mg/mL single-dose vials), also looks similar to the other vials (**Figure 1**), which led to a recent medication error at a different hospital. An anesthesiologist intended to administer a dose of glycopyrrolate 0.2 mg to treat a patient's increased secretions after induction of general anesthesia. However, he reached into the glycopyrrolate matrix pocket in the anesthesia cart and pulled out a vial of naloxone without realizing. It was not until after administration of the medication that the anesthesiologist fully looked at the vial, read "naloxone 0.4 mg/mL," and realized he had administered the wrong medication. Part of the problem may be the yellow background used to highlight the strength for each of these products, as this draws one's eyes away from the drug name. Similar size and shape of the vials and cap colors also likely contribute to mix-ups.

Somerset Therapeutics told us recently that they have revised the label for the naloxone 1 mL vial, but older vials may still be distributed to and stocked in pharmacies. For now, especially in areas where barcode scanning is not available or routinely used, we recommend selectively purchasing one or more of these drugs from a different manufacturer to differentiate the vial appearances.

Figure 1. Vials of naloxone, verapamil, and glycopyrrolate share a similar label design with a yellow background to highlight the strength, as well as similar cap colors and vial sizes.

Special Announcements

FREE international ISMP webinar

Join us on **January 21, 2021**, for a **FREE** webinar on the ***Top Medication Errors Reported to ISMP in 2020***. We encourage our international colleagues to attend! For details and to register, please visit: www.ismp.org/node/21308.

Virtual MSI workshops in 2021

Don't miss a unique opportunity to register for one of our 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshops being offered in 2021 on **February 25 & 26, April 22 & 23, June 24 & 25**, and **August 5 & 6**. For details, visit: www.ismp.org/node/127.

Become an ISMP fellow

ISMP will soon be accepting applications for three unique Fellowship programs that will begin in the summer/fall of 2021. For brief descriptions of the Fellowships, candidate qualifications, brochures, and program outlines, visit: www.ismp.org/node/871. More information about applying for a Fellowship will be provided early in 2021!

Community/ambulatory care survey

If you provide community or ambulatory care, please take a few minutes to complete our short survey on high-alert medications at: www.ismp.org/ext/551 by **January 15, 2021**. Your input is needed to update the *ISMP List of High-Alert Medications in Community/Ambulatory Healthcare*.

To subscribe: www.ismp.org/node/10

ISMP Medication *Safety Alert!* Acute Care (ISSN 1550-6312)

Report medication and vaccine errors to ISMP: Call 1-800-FAIL-SAF(E) or visit our website at: www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

Special Recognition...

Our 2020 ISMP Medication *Safety Alert!* Clinical Advisory Board

Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented Clinical Advisory Board. As 2020 nears an end, we want to thank each of the following members of the Clinical Advisory Board for their dedication to making this newsletter a valuable medication safety resource for clinicians.

- **Ivyruth Andreica**, PharmD, BSN, FISMP, Ivenix, Inc., North Andover, MA
- **Michelle Bell**, RN, BSN, FISMP, CPPS, Patient Safety Authority, Harrisburg, PA
- **Kelly Besco**, PharmD, FISMP, CPPS, OhioHealth, Columbus, OH
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- **Daniel Sheridan**, RPh, MS, CPPS, OhioHealth Marion General Hospital & Hardin Memorial Hospital, Marion, OH
- **Elizabeth Wade**, PharmD, BCPS, FASHP, Concord Hospital, Concord, NH
- **Mandy Wollitz**, PharmD, BCPS, FISMP, AdventHealth Orlando, Orlando, FL

HAPPY Holidays

from the staff, Board of Directors, and Advisory Board
at the Institute for Safe Medication Practices (ISMP).
We wish you joy, health, and happiness this holiday season!